DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 00N–0085]

National Environmental Policy Act; Food Contact Substance Notification System; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 24, 2000, for the direct final rule (DFR) that appeared in the **Federal Register** of May 11, 2000 (65 FR 30352). The DFR amended FDA's regulations on environmental impact considerations. This document confirms the effective date of the DFR.

DATES: Effective date confirmed: August 24, 2000.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a DFR published in the **Federal Register** of May 11, 2000 (65 FR 30352), FDA amended its regulations on environmental impact considerations as part of the agency's implementation of the FDA Modernization Act (FDAMA) of 1997. FDAMA amended the Federal Food, Drug, and Cosmetic Act (the act) by establishing a notification process for authorizing new uses of food additives that are food contact substances. The DFR amended the regulations in 21 CFR 25.20 to add to the list of those actions that require an environmental assessment allowing a notification submitted under section 409(h) of the act (21 U.S.C. 348(h))

to become effective and in 21 CFR 25.32(i), (j), (k), (q), and (r) to expand the existing categorical exclusions from the requirement of an environmental assessment to include allowing a notification submitted under section 409(h) of the act to become effective.

FDA solicited comments concerning the DFR for a 75-day period ending July 25, 2000. FDA stated that the effective date of the DFR would be on August 24, 2000, 30 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period.

FDA received only one comment (from a trade association) on the DFR, which reiterated the association's views presented in response to an agency public meeting held prior to the initiation of this rulemaking. FDA has determined that the received comment is not a significant adverse comment for several reasons. First, in the preamble to the DFR, FDA referenced the association's prior submission and addressed its substance. Second, the comment does not dispute (or even directly address) the analysis presented in the DFR. It raises no new arguments and provides no new information for the agency's consideration. Finally, the association expressly characterizes the comment as not a ''significant adverse comment'' and supports the rule becoming effective as drafted.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby became effective August 24, 2000.

Dated: October 3, 2000.

Margaret M. Dotzel

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Associate Commissioner for Policy

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